

# **EXHIBIT 20**

### Report of NACDS Meeting with DEA – May 3, 2016

Principal representatives from the DEA Office of Diversion Control were **Demetra Ashley** (Associate Deputy Assistant Administrator), **Jim Arnold** (Acting Chief of the Liaison and Policy Section), and **Tom Prevoznik** (Liaison Unit Chief). Ms. Ashley is second in command to **Lou Milione**, who is the head of the Office of Diversion Control. Below are the agenda items that we discussed, and a summary of the discussion.

DEA Field Office Communications: We discussed the long history of inconsistent interpretations and guidance among the various DEA Field Offices. DEA acknowledged this persistent problem, and is increasing their training of DEA Field Office personnel. Moving forward, DEA asks that we attempt to resolve inconsistent communications with the Group Supervisor at the Field Office. If that is not successful in resolving the problem, please report the problem to DEA Headquarters at the following email address: [odlp@usdoj.gov](mailto:odlp@usdoj.gov).

Under this agenda item, we also discussed inconsistent DEA Field Office communications about the DEA regulations for central fill, and the need for DEA to update their central fill regulations. DEA asked NACDS to send a letter to the agency outlining our concerns with the central fill regulations and our recommendations.

Transferring/Forwarding and Electronic Prescription: DEA acknowledged that the regulations for electronic prescribing of controlled substances (EPCS) do not address situations when an electronic prescription (that has never been filled) needs to be re-directed to another pharmacy. DEA is looking into this for the final EPCS rule, and asked us to include this issue in the letter that was mentioned above.

Ensuring Patient Access and Effective Enforcement Act (S. 483): With respect to the legislation's requirement that the agency work with HHS on a report to Congress on how collaboration between law enforcement agencies and the pharmaceutical industry can benefit patients and prevent diversion and abuse of controlled substances, DEA reported that they are aware of this provision and are still working through how they will implement it. They assured us that they will contact us when the time is right for them to engage us on it. DEA stated that it plans to draft proposed rules to implement the enforcement provisions of the new law. The proposed regulations should be issued this summer. Meanwhile, DEA indicated that these enforcement provisions, such as limits on immediate suspension of registration and the right of registrants to submit corrective action plans, are currently in effect.

Formal and Informal Guidance from DEA: We talked about the need for industry to receive timely formal and informal guidance on interpretation of DEA laws and regulations. DEA acknowledged this request and mentioned they are presently clearing a backlog of letters and guidance, including a letter on the changes that a pharmacist may make to a C-II prescription after consulting the prescriber. They said they will do their best to respond to our requests in a timely manner, but they do have a clearance process that guidance must go through before being issued. For example, they have to ensure that the guidance does not relate to ongoing investigations or litigation.

DEA Inspection Process: We spoke with DEA about inconsistent DEA inspections and poorly trained DEA agents. DEA is increasing training of Field Personnel. They mentioned that pharmacies should work with the local DEA supervisor or DPM with specific concerns about inspections.

Responding to DEA Requests: We asked DEA to allow pharmacies to respond to DEA requests for information with electronic records, as opposed to paper records. DEA responded that they need paper records for prosecutorial purposes. They cannot rely on an electronic record instead of a paper record if a paper record exists. Often, they need to marry together the information from the electronic record and paper record.

Drug Disposal Regulations: NACDS members raised a number of concerns about the DEA drug disposal regulations, including the security of the receptacles, the need for two persons to remove and transfer the filled inner liners, and concerns with EPA and DOT requirements. DEA responded with the following comments and information:

- DEA realizes the regulations are not perfect but they do provide one avenue for getting unused controlled substances out of people's homes
- The regulations are voluntary; other locations for drug disposal include law enforcement facilities and long-term care facilities
- A take-back receptacle does not have to be in the line of sight of pharmacy staff but within view of any employee within the retail store as a whole
- DEA will continue to conduct two national take-back events per year
- DEA advised that pharmacies might want to consider directing patients to other locations for drug take-back and disposal, and that there are websites that provide that information including the DEA website
- DEA acknowledged EPA and DOT issues and is working through the issues with those agencies
- DEA advised that full inner liners may be stored behind the pharmacy counter
- Finally, DEA stated that they are grateful for our efforts in helping consumers get rid of unwanted medications

Suspicious Order Monitoring: At the February 29 meeting, DEA mentioned that the agency WOULD soon issue an NPRM on suspicious order monitoring. On May 3, HOWEVER, DEA stated that they will issue guidance on suspicious order monitoring by the end of 2016. With respect to pharmacies that are seeking guidance in this area, DEA recommended that pharmacies utilize the NABP Red Flags Document.

CSOS: NACDS members raised issues with CSOS and the difficult administrative requirements associated with it. DEA responded that they are looking to streamline many of the CSOS requirements, including the re-certification process.

In sum, NACDS had a useful and productive meeting with DEA. Moreover, DEA personnel seemed genuinely interested in hearing and addressing our concerns. Ms. Ashley invited us to meet again with her staff as often as we need to.